QUALITY MANAGEMENT SYSTEM (QMS) ASSESSMENT CHECKLIST

1. QUALITY MANAGEMENT SYSTEM				
1.1 Quality Management System – General	**Y**	**N**	**N/A**	**Assessor Comments**
1.1.1 Is objective evidence available to demonstrate that the MDSAP site has defined, planned, and implemented a quality management system?				
1.1.2 Has the MDSAP site identified the processes needed to implement QMS throughout the organization?				
1.1.3 Have criteria and methods been established to ensure that the operation and control of these processes are effective?				
1.1.4 Has a quality manager with defined responsibility and authority for ensuring that the management system related to quality is implemented and followed been appointed?				
1.2 Quality Management System – Documentation – Control of Documents *MDSAP Quality Manual – Category 2. QMS/Documentation - 2.3.2* *A "Documented procedure" is when it has been written, established, implemented and maintained. Documentation can be in any form or type of medium. Document – ASQ Glossary is defined as information and its supporting medium*	**Y**	**N**	**N/A**	**Assessor Comments**
1.2.1 Are documents required for the quality management system controlled?				
1.2.2 Is there a documented procedure for: Approving documents for adequacy before they are issued?				
1.2.3 Reviewing, updating as necessary and re-approving revised documents?				
1.2.4 Identifying the current revision of documents?				
1.2.5 Ensuring that correct versions of documents are available at to end users?				
1.2.6 Ensuring that documents of external origin are identified and their distribution is controlled?				
1.2.7 Preventing use of obsolete documents, and identifying supplanted documents that are retained?				
1.2.8 Has the established MDSAP Quality Manual been implemented, including: a. Scope of quality system, details and exclusion justifications? b. Procedures or references to procedures? c. Sequence and interaction of processes or reference to them?				
1.3 Quality Management System – Documentation – Control of Records *MDSAP Quality Manual - Category 2. Documentation - 2.3.3*	**Y**	**N**	**N/A**	**Assessor Comments**
1.3.1 Is there a documented procedure to define controls needed for record identification, storage, protection, retrieval, retention time and disposition?				
1.3.2 Is there a procedure to ensure records, including training records, are identified, controlled, updated and				

retrievable?				
1.3.3 Are there procedures covering control of records, i.e. collection reports, analytical worksheets ,establishment inspection reports, warning letters, program reviews, quality reports, equipment data, etc.?				
1.3.4 Are there procedures about maintaining QMS records, i.e. audit reports, corrective actions, nonconformance's, etc.				
1.3.5 Are there procedures covering controls to identify, store, protect, retrieve, retain and dispose of records?				
2. MANAGEMENT RESPONSIBILITY *You can get the information from records, evidence, summary report of audits or logs, notes, agenda/minutes, surveys, complaints and action items logs, and continual improvement reports including customer feedback.*				
2.1 Management Responsibility - Management Commitment *Has top management demonstrated its commitment to the development and improvement of the quality management system by :*	Y	N	N/A	Assessor Comments
2.1.1 Has management demonstrated commitment to the QMS development and improvement by: Communicating to the MDSAP staff the importance of meeting customer as well as regulatory & legal requirements?				
2.1.2 Establishing the quality policy?				
2.1.3 Ensuring that quality objectives are established?				
2.1.4 Conducting management reviews?				
2.1.5 Ensuring availability of resources?				
2.2 Management Responsibility - Customer Focus	Y	N	N/A	Assessor Comments
2.2.1 Does top management ensure that customer requirements are determined and met with the goal to achieve customer satisfaction?				
2.2.2 Are customers and shareholders kept informed?				
2.3 Management Responsibility - Quality Policy	Y	N	N/A	Assessor Comments
2.3.1 Is there an established quality policy?				
2.3.2 Has top management ensured that the quality policy is communicated and understood within the component?				
2.3.3 Is the quality policy included in the document control process?				
2.4 Management Responsibility - Strategic and Quality Planning	Y	N	N/A	Assessor Comments
2.4.1 Are there established quality objectives?				
2.4.2 Is the quality management system planning carried out to meet the requirements of the quality management system and the quality objectives?				

2.4.3 If applicable, Is there evidence that the integrity of the quality management system is maintained during changes?				
2.5 Management Responsibility - Responsibility and Authority	Y	N	N/A	Assessor Comments
2.5.1 Are functions and their interrelations within the MDSAP site defined and communicated?				
2.5.2 Are responsibilities and authorities defined?				
2.5.3 Is an individual appoints who has the responsibility and authority for ensuring QMS establishment, implementation, and maintenance?				
2.6 Management Responsibility – Internal Communication	Y	N	N/A	Assessor Comments
2.6.1 Is there communication between various levels and functions with respect to the processes of the management system?				
2.6.2 Does that communication address the effectiveness of the management system?				
2.7 Management Responsibility - Management Review *MDSAP Quality Manual – Category 3. Management Responsibility - 3.7*	Y	N	N/A	Assessor Comments
2.7.1 Does top management review the quality management system at planned intervals, to ensure continued suitability, adequacy, and effectiveness?				
2.7.2 Are opportunities for improvement in the system assessed? ✓ If yes, how often?				
2.7.3 How are opportunities for improvement and needed change in the quality system evaluated and documented?				
2.7.4 Do managers review: audit results, customer feedback, process performance, product conformity, preventive and corrective actions, follow-ups to prior management reviews, changes that could affect the quality management system, and recommendations for improvement? ✓ If yes, are they recorded, maintained and subsequent actions monitored?				
2.7.5 Do reviews evaluate the need to change the quality management system, including quality policy and quality objectives?				
3. RESOURCE MANAGEMENT				
3.1 Provision of Resources	Y	N	N/A	Assessor Comments
3.1.1 Is objective evidence available to demonstrate that the MDSAP site has adequate resources needed to implement the quality management system and to maintain its effectiveness?				
3.1.2 Has the MDSAP site provided adequate resources to improve the effectiveness of the quality management system?				

3.1.3 Has the MDSAP site available resources to enhance customer satisfaction by meeting customer requirements?				
3.2 Human Resources – General	Y	N	N/A	Assessor Comments
3.2.1 Are personnel performing work affecting quality competent on the basis of appropriate education, training, skills, and experience?				
3.3 Human Resources – Competence, Awareness, and Training	Y	N	N/A	Assessor Comments
3.3.1 Has the MDSAP site determined the necessary competence for personnel performing activities affecting product quality?				
3.3.2 Are personnel who have been assigned QMS responsibilities qualified and deemed competent based on skills, experience, and education & training requirements? ✓ If yes, describe under comments how the organization: (3.3.3 - 3.3.7)				
3.3.3 Determined the necessary requirements?				
3.3.4 Provided training to satisfy competency needs?				
3.3.5 Evaluated effectiveness of competence training?				
3.3.6 Ensured that personnel are aware of their role in the QMS?				
3.3.7 Maintained appropriate records of education, training, skills, and experience?				
4. WORK PROCESSES, CONTROLS, AND EXECUTION				
4.1 Planning Work Processes	Y	N	N/A	Assessor Comments
4.1.1 Has the MDSAP site planned and developed the processes needed for their products?				
4.1.2 Is objective evidence available to demonstrate that the MDSAP site ensures changes in plans are appropriately controlled?				
4.1.3 In planning, has the MDSAP site identified the process acceptance criteria for the product based on known requirements?				
4.1.4 Is objective evidence available to demonstrate that the MDSAP site designs and develops new work processes in a manner that takes into account the impact on related work and the ability to meet customer requirements?				
4.1.5 Are adequate resources and information available to support the operation and monitoring of these processes?				
4.2 Work Plans and Assignments	Y	N	N/A	Assessor Comments
4.2.1 Does the MDSAP site document review and acceptance of work and assignments?				
4.2.2 Does the MDSAP site document communication with customers (i.e. assignment status and outcomes, changes/amendments made to plans or assignments, complaints and actions related to nonconformities) for work planning and the review, issuance, and acceptance of assignments?				

4.3 Contracting Work	Y	N	N/A	Assessor Comments
4.3.1 Is objective evidence available to demonstrate that the MDSAP site ensures that contracting processes and documented procedures provided to and explained to contractor?				
4.3.2 Is objective evidence available to demonstrate that the MDSAP site places contracts with a competent contractor in order to achieve equivalent level of quality control as if MDSAP staff performed the work?				
4.3.3 Is objective evidence available to demonstrate that the MDSAP site ensures that the contractor complies with a comparable quality system for the work in question?				
4.3.4 Is objective evidence available to demonstrate that contracts are reviewed and approved based on adequate specification of work and quality requirements?				
4.3.5 Are procedures established to ensure that when work is contracted rather than performed by MDSAP, MDSAP will advise in writing and, when appropriate, gain the approval of the customer?				
4.4 Control of Equipment and Materials	Y	N	N/A	Assessor Comments
4.4.1 Is a procedure established to ensure equipment and materials needed to meet work and method requirements are identified and selected?				
4.4.2 Is objective evidence available to demonstrate that the procedure established for meeting equipment and materials is implemented?				
4.4.3 Are procedures established by the MDSAP site to ensure staff is provided with methods for handling, preservation, and storage to protect equipment and materials from damage or deterioration and to maintain their integrity?				
4.4.4 Are procedures established by the MDSAP site to ensure equipment and materials are uniquely identified as needed to meet traceability requirements and traceability records are maintained by MDSAP?				
4.4.5 Are procedures established by the MDSAP site to ensure that if equipment or materials are found to be improperly functioning, the MDSAP site ensures the validity of the work previously performed with the equipment or materials is assessed, and appropriated actions are taken if fitness for use is compromised?				
4.5 Operations	Y	N	N/A	Assessor Comments
4.5.1 Is objective evidence available to demonstrate that the MDSAP site's management ensures that the MDSAP staff uses defined procedures for performing work, for assuring work is reproducible, and for maintaining information integrity?				
4.5.2 Are work activities performed according to established procedures and methods (i.e. define work product requirements, specify procedural steps to a degree necessary for proper performance by competent personnel, describe equipment used for processing/measuring/monitoring, and instruct how product is delivered to the customer)?				
4.5.3 Are there defined procedures used to perform quality control activities and to report non-conformances in accepted work products?				
4.6 Operations – Verification and Validation of Work Processes	Y	N	N/A	Assessor Comments

4.6.1 Do the product and its associated work processes have defined acceptance criteria, monitored to verify that the product and customer requirements are met?				
4.6.2 Is there written procedures indicating when a work process or product does not meet standard practice or is significantly modified due to unusual circumstances whereby the MDSAP site supervisors ensure the impact of the non-conformity is evaluated in regards to meeting customers needs?				
4.7 Operations – Integrity, Traceability and Identification	Y	N	N/A	Assessor Comments
4.7.1 Are work products clearly, or when necessary, uniquely identified?				
4.7.2 Is the relevant information recorded regarding the personnel, materials, equipment, chronology, methods and environment associated with a work activity for traceability purposes (as applicable)?				
4.7.3 Is the customer informed of the issues relating to the fitness-for-use and regulatory compliance when integrity is compromised or uncertain?				
4.8 Reporting Results	Y	N	N/A	Assessor Comments
4.8.1 Is there objective evidence available to demonstrate that requirements for reports are set so that work results may be reported accurately, clearly, unambiguously, objectively, and in accordance with specific directives?				
4.8.2 If applicable, are approved non-conformances to procedures identified in report?				
4.8.3 Do written reports that express opinions and interpretations also contain the basis upon which the opinions and interpretations have been made?				
4.8.4 Is information needed for traceability or evaluation not included in a report is readily available to the performing MDSAP site and are reports that are stored other than with the performing MDSAP site are readily retrievable?				
4.8.5 Is non-MDSAP information used in reports clearly identified?				
4.8.6 Is the integrity and accountability maintained for reports when reports that are transmitted via telephone, facsimile or other electronic or electromagnetic means?				
4.8.7 Are material amendments to an issued report made as an additional report or data transfer in accordance with established procedures?				
5. QUALITY MEASUREMENT, ACCEPTANCE, AND IMPROVEMENT				
5.1 Measurement, Analysis and Improvement – General	Y	N	N/A	Assessor Comments
5.1.1 Is objective evidence available to demonstrate that the MDSAP site has defined, planned, and implemented the monitoring and measurement activities needed to assure conformity and to achieve improvement?				
5.2 Measurement, Analysis and Improvement - Monitoring and Measurement - Customer Satisfaction *MDSAP Quality Manual – Category 6. Quality Measurement, Acceptance, and Improvement/Measurement*	Y	N	N/A	Assessor Comments

planning and implementation - 6.1.1 *Level I – received from within the MDSAP site; Level II received from other MDSAP components; Level III received from outside MDSAP Site. To serve its customers and stakeholders we need to monitor the information and data on satisfaction regarding requirements being met.*				
5.2.1 Is there a documented procedure for complaints and feedback? ✓ If yes, do procedures require: (5.2.1 – 5.2.4)				
5.2.2 Receiving, documenting and categorizing complaints and feedback				
5.2.3 Processing and monitoring complaints to closure				
5.2.4 Including complaints/feedback in audits and internal management reviews to ensure that follow-ups were effective in correcting the root problem causes?				
5.2.5 Tracking and trending complaint data in the MDSAP site's CAPA system? ✓ If yes, are trending results parts of management review?				
5.2.6 Is customer satisfaction information recorded and monitored?				
5.2.7 Is customer feedback analyzed for trends and improvements?				
5.3 Measurement, Analysis and Improvement - Monitoring and Measurement - Internal Audit *MDSAP Quality Manual – Category 6. Quality Measurement, Acceptance, and Improvement - 6.5* *Internal audits responsibilities and requirements. Includes schedule, audit reports, verification of actions*	Y	N	N/A	Assessor Comments
5.3.1 Are periodic internal audits performed to determine if the quality management system has been effectively implemented and maintained?				
✓ If yes, does the auditing MDSAP site consider results of previous audits?				
5.3.2 Do follow-ups verify corrective action implementation and effectiveness?				
5.3.3 Are audits conducted by people other than those who performed activities being audited?				
5.3.4 Is there a documented procedure that includes responsibilities and requirements for conducting audits? ✓ If yes, are the audit scope, frequency and methodologies defined?				
5.3.5 Are there documented procedures that include the responsibilities and requirements for conducting audits, ensuring their independence, recording results, and reporting to management?				
5.3.6 Have auditors been trained?				
5.3.7 Are records of auditor training maintained and available?				
5.3.8 Does management take timely corrective action on deficiencies found during audits? ✓ If yes, do follow-ups verify and document corrective action implementation?				
5.4 Measurement, Analysis and Improvement - Monitoring and Measurement - Monitoring and Measurement of Processes	Y	N	N/A	Assessor Comments

5.4.1 Have the key quality management system processes, especially the product realization processes, needed to meet planned results been identified?				
5.4.2 Are suitable methods used to measure and monitor these key processes?				
5.4.3 Are the intended purposes of the key processes quantified by process parameter specifications, by specifications for the product output of the process or by some other means?				
5.5 Measurement, Analysis and Improvement - Monitoring and Measurement - Monitoring and Measurements of Product	Y	N	N/A	Assessor Comments
5.5.1 Does the MDSAP site measure and monitor product characteristics to verify that product requirements have been met?				
5.5.2 Does the MDSAP site measure and monitor product characteristics at appropriate stages of the product realization process?				
5.5.3 Is there objective evidence that acceptance criteria for product have been met?				
5.5.4 Do records identify the person authorizing release of the product?				
5.5.5 Are all specified activities performed before product release and service delivery?				
5.5.6 If there are instances in which all specified activities have not been performed before product release or service delivery, has a relevant authority, or as appropriate the customer, been informed and approved of the action?				
5.6 Measurement, Analysis and Improvement – Control of Nonconforming Product *MDSAP Quality Manual – Category 6. Quality Measurement, Acceptance, and Improvement - 6.2* *Record required. (Nature of the product nonconformities and any subsequent actions taken) Procedure required. (Control of nonconformity)*	Y	N	N/A	Assessor Comments
5.6.1 Does the MDSAP site ensure that a non-conforming product is identified and controlled to prevent unintended use or delivery?				
5.6.2 Are these activities defined in a documented procedure?				
5.6.3 Is nonconforming product corrected and subjected to re-verification after correction to demonstrate conformity?				
5.6.4 I When nonconforming product is detected after delivery or use has started, is appropriate action taken regarding the consequences of the nonconformity?				
5.7 Measurement, Analysis and Improvement - Analysis of Data	Y	N	N/A	Assessor Comments
5.7.1 Does the MDSAP site analyze the data to determine the suitability and effectiveness of the quality management system?				
5.7.2 Does the MDSAP site analyze data to identify improvements that can be made?				
5.7.3 Does the MDSAP site analyze data to provide information on customer satisfaction?				
5.7.4 Does the MDSAP site analyze data to provide information on conformance to product requirements?				

5.7.5 Does the MDSAP site analyze data to provide information on trends?				
5.8 Measurement, Analysis and Improvement - Improvement - Continual Improvement *MDSAP Quality Manual – Category 6. Quality Measurement, Acceptance, and Improvement - 6.8* *Related to management review, internal audits, CA/PA reports, and process/program improvements*	Y	N	N/A	Assessor Comments
5.8.1 Analysis of Data: Are appropriate data collected and analyzed to determine quality management system suitability and effectiveness, and to identify possible improvements?				
✓ If yes, do data include measuring and monitoring activities?				
5.8.2 How are data analyzed to provide information on:				
a. Customer satisfaction and/or dissatisfaction?				
b. Conformance to customer requirements?				
c. Characteristics of processes, products, and trends of quality characteristics?				
d. Contractors' performance?				
5.8.3 Is objective evidence available to demonstrate that arrangements are planned for verification of work quality, verification is implemented and records of the contractor's performance are maintained?				
5.8.4 Is objective evidence available to demonstrate that when the MDSAP site discovers nonconformities in the work performed by the contractor, the MDSAP site documented a corrective action and provided feedback and retrained as appropriate?				
5.8.5 Is objective evidence available to demonstrate that the MDSAP site ensures agency contracting processes and documented procedures are used to ensure that contractor produced work conforms to MDSAP requirements for work process and work product?				
5.8.6 Are processes to achieve continuous improvement of the quality management system planned and managed?				
5.8.7 Is there objective evidence available to demonstrate that reports account for all information requested by the customer and necessary for the interpretation of results?				
5.8.8 How is continual improvement of the quality management system facilitated through:				
a. Quality policy?				
b. Quality objectives?				
c. Audit results?				
d. Analysis of data?				
e. Corrective and preventive actions?				
f. Management review?				
5.9 Measurement, Analysis and Improvement - Improvement - Corrective Action *MDSAP Quality Manual – Category 6. Quality Measurement, Acceptance, and Improvement - 6.6* *Corrective action related to Customer complaints, Customer Dissatisfaction, Non-conformance reports,*	Y	N	N/A	Assessor Comments

evaluation, Management review and Review of past CA/PA records				
5.9.1 Are corrective actions taken in a manner to eliminate the cause of nonconformities, so as to prevent their recurrence?				
✓ If yes, how is corrective action appropriate to the impact of the problem(s) encountered?				
5.9.2 Are there documented procedures for corrective actions?				
✓ If yes, do procedures require:				
a. Identifying nonconformities, including those contained in customer complaints?				
b. Determining causes of nonconformity?				
c. Evaluating the need for actions to ensure nonconformities don't recur?				
d. Determining and implementing corrective actions needed?				
e. Recording results of corrective actions?				
f. Reviewing corrective actions taken to determine their effectiveness?				
5.9.3 Do procedures ensure relevant information on corrective actions is submitted for management review?				
5.10 Measurement, Analysis and Improvement - Improvement - Preventive Action *MDSAP Quality Manual – Category 6. Quality Measurement, Acceptance, and Improvement - 6.7* *Preventive action related to Process/Program evaluation for improvement, actions taken, Management review (past/present)*	Y	N	N/A	Assessor Comments
5.10.1 When appropriate, are preventive actions identified to eliminate the causes of potential nonconformities? If yes, are preventive actions taken appropriate to the impact of the potential problems?				
5.10.2 Are there documented procedures for preventive actions?				
✓ If yes, do procedures include::				
a. Identifying potential nonconformities and their causes?				
b. Determining and ensuring that preventive actions are implemented?				
c. Recording results of actions taken?				
d. Reviewing preventive action taken?				
5.10.3 Do the procedures ensure relevant information on action taken is submitted for management review?				